NDA 12-141/S-086
NDA 12-142/S-103

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

JAN 30 2001

Attention: Joseph A. Linkewich, Pharm.D.
Director, Regulatory Science

Dear Mr. Linkewich:

Please refer to your supplemental new drug applications dated March 10, 2000, received March 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CYTOXAN Tablets (cyclophosphamide tablets, USP), and Lyophilized CYTOXAN for Injection (cyclophosphamide for injection, USP).

We also refer to your final printed labeling (FPL) submitted October 18, 2000. We note that this labeling incorporates the changes made in NDA 12-141/S-086 and NDA 12-142/S-103.

These "Changes Being Effected" supplemental new drug applications provide for an addition to the **ADVERSE REACTIONS** section of the package insert which is based on events identified from ongoing post-marketing surveillance.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

We note that the final printed labeling (FPL) submitted October 18, 2000, supercedes the FPL submitted with these supplements on March 10, 2000.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research